

3. Guidelines for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)

Summary/ Performance Objective – Aim

The Living Donor Committee is proposing a set of guidelines for the medical evaluation of living kidney donors. The guidelines include recommendations for the psychosocial evaluation of living donors, relative and absolute contraindications to living donation, and suggestions for living donor follow-up.

Background and Significance

In January 2007, the UNOS President sent a letter to all transplant programs that perform live donor transplants requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The letter explained that Federal regulation now required the Organ Procurement and Transplantation Network (OPTN) to develop policies for the equitable allocation of living donor organs. The Living Donor Committee planned to use these protocols to make recommendations to the OPTN/UNOS Board of Directors regarding new living donor guidelines.

The committee members reviewed and assessed all submitted protocols. Their evaluation revealed wide variation in the medical evaluation of potential living kidney donors. Some centers even lacked any formal guidelines for the medical evaluation of a living donor. Additionally, the Committee reviewed recommendations from the American Society of Transplantation (AST), completed an extensive literature review (Exhibit A), and completed a focused survey of 16 large transplant centers in the development of these guidelines (Exhibit B).

The Living Donor Committee proposes these guidelines as an important step in the protecting the health and safety of all living donors.

Proposal

Guidelines for the Medical Evaluation of Living Kidney Donors

Purpose

The OPTN/UNOS Living Donor Committee developed these guidelines to help transplant professionals medically evaluate potential living kidney donors

Introduction

An important step in the medical evaluation of living kidney donors is education about the medical evaluation process. The Independent Donor Advocate (IDA) or Independent Donor Advocate Team, which determines a candidate's suitability for donation, coordinates the medical evaluation of a potential living donor. The potential donor can stop the evaluation or donation process at any time and the medical team may be obligated to state that the donor is not an acceptable candidate without providing specific reasons for this decision.

LIVING DONOR PSYCHOSOCIAL EVALUATION

Goals of the psychosocial evaluation:

- a. To identify and appraise any potential risks for poor psychosocial outcome, including risks related to the individuals psychiatric history or social stability.
- b. To ensure that the prospective donor comprehends the risks, benefits and potential outcome of the donation for herself or himself and the recipient, and that the donor understands that the data on long-term donor psychosocial outcomes continue to be sparse.
- c. To assess the donor's capacity to make the decision to donate and ability to cope with the major surgery and related stress.
- d. To assess donor motives and the degree to which the donation decision is made free of guilt, undue pressure, enticements or impulsive responses.
- e. To review lifestyle circumstances (e.g., employment, family relationships) that might be affected by donation.
- f. To determine that support systems are in place and ensure a realistic plan for donation and recovery, with adequate social, emotional and financial support and resources.
- g. To identify any factors that warrant educational or therapeutic intervention before donation can proceed. The team needs to identify the donors anxiety, depression and mental conditions as well as any unsafe reasons for wanting to donate.

Key personnel for the psychosocial evaluation.

1. A licensed social worker, psychologist and/or psychiatrist familiar with the transplant process should perform the psychosocial evaluation of the living donor candidate. Whenever possible the person conducting the evaluation should be independent of the transplant program.

The evaluator should have at a minimum a master's level education. The evaluation should include an assessment of donor's understanding of the entire donation process. The evaluation should also include an assessment of the donor's anxiety and depression levels and the donor's ability to cope with stress and a possible poor outcome.

2. Members of the donor team should have access to the living donor assessment, yet the assessment should not be included in the recipients chart. It is necessary to exclude this report from the recipient's records because the donor is doing this voluntarily and for no personal medical benefit.

3. The prospective donor must be advised that the information contained in the report will be subject to the same regulations as regular medical records and cannot be additionally protected. In order to protect the donor as much as possible the more sensitive questions should be at the end of the psychosocial evaluation. Therefore, if the evaluator determines earlier in the evaluation that the individual is not an appropriate candidate, the more sensitive questions will not be asked and the answers will not appear in the report.

Include the following components to complete the psychosocial evaluation:

- a. History and current status: Obtain standard background information such as the prospective donor's educational level, living situation, cultural background, religious beliefs and practices, significant relationships, family psychosocial history, employment, lifestyle, community activities, legal offense history and citizenship.
- b. Capacity: Ensure that the prospective donor's cognitive status and capacity to comprehend information are not compromised and do not interfere with judgment; determine risk for exploitation.
- c. Psychological status: Establish the presence or absence of current and prior psychiatric disorder, including but not limited to mood, anxiety, substance use and personality disorders. Review current or prior therapeutic interventions (counseling, medications); physical, psychological or sexual abuse; current stressors (e.g. relationships, home, work); recent losses; and chronic pain management. Assess repertoire of coping skills to manage previous life or health-related stressors.
- d. Relationship with the transplant candidate: Review the nature and degree of closeness (if any) to the recipient, (i.e., how the relationship developed); and whether the transplant would impose expectations or perceived obligations on the part of either the donor or the recipient.
- e. Motivation: Explore the rationale and reasoning for volunteering to donate, i.e. the 'voluntariness', including whether donation would be consistent with past behaviors, apparent values, beliefs, moral obligations or lifestyle. Determine whether it would be free of coercion, inducements, ambivalence, impulsivity or ulterior motives (e.g. to atone or gain approval, to stabilize self-image, or to remedy a psychological malady).
- f. Donor knowledge, understanding and preparation: Explore the prospective donor's awareness of the following:
 - any potential short- and long-term risks for surgical complications and health outcomes, both for the donor and the transplant candidate
 - recovery and recuperation time
 - availability of alternative treatments for the transplant candidate
 - financial ramifications (including possible insurance risk).

Make sure that the donor understands that data on long-term donor health and psychosocial outcomes continue to be sparse. Assess the prospective donor's understanding, acceptance and respect for the specific donor protocol, e.g. willingness to accept potential lack of communication from the recipient and the donor's willingness to undergo future donor follow-up.

g. Social support: Evaluate support networks available to the prospective donor on an ongoing basis as well as during the donor's recovery from surgery. Consider significant others, family members, social contacts and employers.

h. Financial suitability: Determine whether the prospective donor is financially stable and free of financial hardship; has resources available to cover financial obligations for expected and

unexpected donation-related expenses; is able to take time away from work or established role, including unplanned extended recovery time; and has disability and health insurance.

i. Tool: The appendix includes tools for the psychosocial assessments of living donors, and suggested post donation questions.

LIVING KIDNEY DONOR MEDICAL EVALUATION

Introduction

The goal of the medical evaluation is to limit postoperative morbidity and mortality and to diminish the risk for long term End Stage Renal Disease (ESRD) and morbidity. Although the real risk of donation in a multiethnic population is not known, UNOS data shows the following:

- the risk of dying from living donor surgery is 0.04%.
- the risk of end stage kidney disease, and the need for dialysis or to receive a kidney transplant is between 0.10 to 0.52%.
- this risk may be higher if the prospective donor is African American.
- of the 81,960 living kidney donors since 1987, 36 (0.04%) have been listed for transplant
- between January, 1996 and February, 2007, 146 previous living donors have been on the kidney waiting list
- for those donors where the date of donation is known (121), the median time from donation to listing is 20 Years.
- living Donor follow-up in Sweden reveals the risk of kidney failure is 0.5% after 30+ years for the all-Caucasian donor population.

In addition, the goal of the evaluation is to ensure that medical conditions that require treatments that necessitate all of the donor's renal function are not present. These conditions include HCV, HIV, cancer and vascular disease. Lastly, the evaluation needs to assess the risk of transmission of disease to the recipient that would negatively impact his/her life.

Evaluation

a. Donor typing to determine the risk for acute transplant failure

- ABO blood group typing x 2
- Human Leukocyte Antigen (HLA) typing
- Cross match

b. General History and Physical Examination

Conduct a general exam as well as a history with a focus on the following:

- family history of kidney disease
- diabetes
- hypertension (high blood pressure)
- birth weight if possible
- gestational diabetes
- birth weight of offspring (for women)
- clotting disorders or deep venous thrombosis
- use of NSAID's anti-inflammatory agents (e.g., ibuprofen, indomethacin),
- urinary tract infections
- nephrolithiasis (kidney stones)
- chronic infections
- kidney injury
- cancer
- heart disease
- lung disease

Determine if prospective donors have dental coverage and whether they have had a recent dental evaluation.

- Physical Examination to include:
- blood pressure (x3 at 3 different times; if possible it is preferable to perform a 24-hour blood pressure monitor)
- height
- weight
- calculated body mass index
- waist circumference
- a search for evidence of heart, lung, liver and blood vessel disease, and abnormal lymph nodes and large spleen

Medical Psychological Evaluation and Social History should include questioning about:

- alcohol intake
- smoking history
- substance use and abuse
- history of mental illness and treatment used

c. General Laboratory Tests

- CBC with platelet count
- Prothrombin Time/Partial Thromboelastin Time (more detailed evaluation with history of coagulation disorders)
- comprehensive panel (electrolytes, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin)
- HCG quantitative pregnancy test women < 55 years old,
- urine toxicology screen

- SPEP in those over 60

d. Cardiovascular – Heart and Blood Vessel tests

- Chest X-Ray,
- Electrocardiogram (ECG),
- ECHO and/or exercise stress test if the prospective donor is over 50 years old or has risk factors (hypertension, smoking, hyperlipidemia, family history, shortness of breath from exercise) or physical findings that demonstrate increased risk for heart disease including the following but not limited to borderline blood pressure, abnormal ECG abnormal CXR, murmur
- Pulmonary function tests for smokers

e. Renal Focused Evaluation

- Urinalysis – look for protein and cells in the urine
- Perform urine culture (if symptoms are present or urinalysis is abnormal)
- Protein excretion: 24 hour urine for protein and/or microalbumin excretion or protein:creatinine ratio and/or albumin:creatinine ratio x 2, if one is abnormal repeat again. If protein is detected, evaluate for postural proteinuria by collecting split urine over 24 hours (8 of those hours recumbent, 16 active)
- Serum creatinine
- Glomerular filtration rate (GFR) measurement – clearance testing, 24 hour urine for creatinine clearance measurement or preferably a measured clearance using urine or plasma clearance of iothalamate, iohexol or other suitable marker. GFR should be expressed per 1.73m^2 . Calculated GFR measurements using the serum creatinine are not felt to be adequate. GFR should be within 2 Standard Deviations for age or be calculated to be at $40\text{cc/min}/1.73\text{m}^2$ at age 80

Screen for PKD as indicated by family history, US if over 30 years old, genetic testing if younger than age 30.

f. Metabolic Focused Evaluation

- Fasting blood glucose
- Uric acid
- Thyroid Stimulating Hormone (TSH)
- Fasting lipid profile (Cholesterol, Triglycerides, HDL Cholesterol, LDL Cholesterol)
- Determine the number of elements of the metabolic syndrome present, consent for risk if ≥ 3 risk factors
- If at increased risk for diabetes (family history of diabetes, gestational diabetes, or elevated triglyceride levels) perform an Oral Glucose Tolerance Test and include calculations for insulin secretion/insulin resistance index, and HBG A1C

g. Infection

- CMV, EBV, HSV, VZV (herpes group virus testing)
- HIV 1,2 (human immunodeficiency viruses)
- HTLV I AND HTLV II (human T-cell leukemia virus)
- HBsAg (Hepatitis B test)
- HBcAB (Hepatitis B test)
- HBSAB (Hepatitis B test)
- HCV (hepatitis C virus)
- RPR (for syphilis)
- Tuberculosis
- Toxoplasmosis (depending upon exposure risk)
- Geographically determined testing
 - Coccidiomycosis
 - Strongyloides
 - Trypanosoma cruzi
 - Malaria
 - HHV-8
- Consider West Nile and HHV-6

h. Anatomic Evaluation

Determine which kidney is the safest to remove and which has the best function and should remain with the donor. Also determine the presence of abnormal liver, nodes, adrenal glands and spleen.

1. The test of choice will depend upon the local radiological expertise and surgical preference but may include CT angiogram, MR Angiogram or angiogram. An abdominal ultrasound may be necessary to evaluate the liver for fatty infiltration and unexpected abnormalities of the liver, pancreas and spleen if a full abdominal CT or MRI are not performed.

2. Renal scan with differential renal function.

i. Cancer Screening

Determines that the donor does not need both kidneys to help with tolerance of anti-cancer treatment and that the donor does not have a tumor that would be transferred to the recipient.

Testing to be performed depending upon gender, age or family history includes:

- PAP for all women
- Mammogram for all women over 40 years old or according to family risk,
- PSA for all men over 50; for all African American men over 40 or if from a high risk family
- Colonoscopy for all donors over 50 years old or younger according to family history, and
- Chest CT for those with a history of smoking.

CONTRAINDICATIONS TO LIVING DONATION

The following reasons could exclude a living donor candidate from donating based upon scientific data for medical risk, psychological assessment and/or consensus on best practice.

Absolute Exclusion Criteria:

- Age < 18 years
- Hypertension BP > 130/90 in someone younger than 50 years old, evidence of end organ damage, non-Caucasian, on three or more anti-hypertensive medications
- Diabetes (diagnosis of diabetes)
- Abnormal glucose tolerance test 2 hour OGTT > 140
- History of thrombosis or embolism
- Psychiatric contraindications
- Obesity: BMI > 35kg/m²
- Coronary Artery Disease
- Symptomatic Valvular Disease
- Chronic lung disease with impairment of oxygenation or ventilation
- Recent malignancy, or cancers with long times to recurrence eg., breast cancer
- Urologic abnormalities of donor kidney
- Creatinine clearance < 80 ml/min/1.73m², or projected GFR with removal of one kidney at 80 years old of < 40 cc/min/1.73m²
- Peripheral vascular disease
- Proteinuria > 300 mg/24 hours
- HIV infection
- Hepatitis C Virus infection
- Hepatitis B Virus infection

Relative Contraindications

- Age 18-21 years old ; older age relative to the medical condition
- Obesity (BMI 30-35)
- Kidney stones
- Distant history of cancer
- Past history of psychiatric disorder
- Renovascular Disease
- Thin basement membrane disease
- Prior valve surgery
- Moderate Cardiac Valvular Disease with otherwise normal echocardiographic findings and
- Mild sleep apnea without pulmonary hypertension

Living Donor Follow-up

After donation occurs, the transplant center must follow the living donor for two years. The donor may have examinations at the center or may choose to visit another facility and have the evaluation results sent to the transplant center.

When donors are discharged from the hospital, they will receive information to help optimize their health status. The donor's primary physician will receive a letter informing them that the donor will require specific testing done at six months, one and two years after donation and that this testing should continue

annually for the rest of their life. Specific information in the donor's post donation instruction packet will include standards for exercise, diet and target weight.

A specific schedule will outline medical follow-up timing, examinations and testing, and an appointment for follow up at the transplant center. Included with the medical evaluation should always be a psychosocial assessment.

The medical testing following donation should include a physical exam with blood pressure measurement and weight, blood tests to include a hematocrit/hemoglobin, creatinine, blood urea nitrogen and fasting glucose and a urinalysis to include a microalbumin measurement at six months and then yearly following donation. In addition yearly fasting lipid profiles should be performed and consideration should be given to performing more formal and exact glomerular filtration rate testing.

Appendix

1. Rationale for Interview of the Donor's Support Person
2. Suggested Follow-up Psychosocial Questions for Living Donors
3. Resource Documents

1. Rationale for Interview of the Donor Support Person

- 1.) It allows for corroboration with a collateral that the donor is free from coercion to donate and to explore other legitimate objections the support person may raise.
- 2.) It allows for an exploration about family attitudes about donation, particularly if important others support donation.
- 3.) It allows for an exploration about family attitudes about the donor and the recipient.
- 4.) It allows for an exploration about family pressures and conflicts.
- 5.) It allows for some verification of the accuracy and the veracity of the donor's self-reports regarding self-care and habits of health maintenance.
- 6.) It allows verification of the process in which the donor has come forward to donate.
- 7.) It allows for an assessment of the type of supports that are available to the donor after surgery and upon discharge.
- 8.) It provides an opportunity for someone to voice concerns that the potential donor may overlooking or be reluctant to voice.
- 9.) It creates a relationship between the medical team and the donor's support before surgery, rather than after surgery when the donor is indisposed.
- 10.) It allows for the support person to get information about the assistance the donor will require after surgery, providing plenty of time to plan for the donor's needs after surgery.

2. Suggested Post Living Donation Donor Psychosocial Follow-up Questions

Psychosocial follow-up questions:

Are you feeling sad, down, depressed or hopeless?

Do you have interest and take pleasure in doing things, especially in things that have been interesting or pleasurable in the past?

Do you feel low energy or speeded up at times, like feeling agitated or having too much energy?

Are you eating or sleeping more or less than you should?

Are you feeling confused or forgetful, or having trouble concentrating which impacts your ability to read, enjoy t.v., or engage in conversation?

Do you feel worried, scared, angry, or upset about anything?

Do you feel let down or disappointed?

Do you find yourself pulling away from people?

Do you feel numb, detached, or as if you are floating?

Are you having thoughts and memories you can't get out of your head?

Do you have aches and pains that are bothersome and can't be explained?

Are you drinking, smoking, or using other types of drugs more than you should?

Are you getting along with family and friends as well as you would like? Are you having arguments or fights, or yelling?

Are you experiencing any problems with finances, family, friends, or work?

Do you feel that the people most important to you understand you and your needs right now?

Do you have thoughts of hurting yourself?

Do you have thoughts of hurting someone else?

If you qualified for short-term disability benefits during your recovery, have you received them?

Are you having trouble performing daily tasks needed to work, go to school, or take care of children?

Were there any experiences (good or bad) in the entire process of donating an organ that you would like to tell us about or that we should know about?

Have your thoughts and feelings about health care providers changed since the transplant?

Do you feel you are getting the help you need for an optimal recovery?

Do you have any medical concerns related to the transplant that you would like the transplant team to address?

Are you comfortable with the arrangements that have been made for your follow-up care?

Can the transplant team help address any of the concerns you have mentioned today?

3. Resource Documents

Screening of donor and recipient prior to solid organ transplantation. Am J Transplant. 2004 Nov;4 Suppl 10:10-20.

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